

GOVERNMENT OF ANDHRA PRADESH
ABSTRACT

Department of AYUSH – Streamlining the system for licensing of patent & proprietary products of Ayurveda Siddha and Unani (ASU) – Expert Committee Constituted – Guidelines for licensing the Ayurvedic Proprietary and patent medicines – Orders – Issued.

HEALTH MEDICAL & FAMILY WELFARE (R2) DEPARTMENT

G.O.Ms.No.95

Dated:21-04-2009

Read the following:

- 1.G.O.Ms.No.230, HM & FW (R2) Dept., dt. 1-7-08.
- 2.From the Commr., Dept. of AYUSH, Hyd., Lr.No.2842/DA/08, dt.23-9-08.

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ORDER:

In the reference first read above, orders were issued constituting an Expert Committee with Chairman and other members to Streamline the system for licensing of patent and proprietary products.

2. The Commissioner, Department. of AYUSH, Hyderabad vide reference 2nd read above has informed that an EPC meeting was conducted to verify and approve certain Ayurvedic Drugs as additional products to Manufactures and to sale under their Licenses as per D&C Rules 1940. The Members of the Committee proposed certain guidelines for licensing the Ayurvedic proprietary and patent Medicines. Government after careful examination of the matter, hereby decide and accordingly formulate the following guidelines for licensing the Ayurvedic proprietary and patent medicines:-

1. The references of ingredients pertaining to the formulation should be provided only from books mentioned in schedule.1 of D&C Act 1940.
2. Chemical Analysis reports like TLC / HPTLC / HPLC should be submitted along with datagraph / photos as evidence pertaining to the products submitted along with license application. Reports can be provided from any Govt. / State Govt. approved labs. / own laboratories. The Pharmacopeial Guidelines / Parameters available from time to time should be utilized wherever available.
3. Authentic purifactory procedures for the drugs belonging to the group of Rasas, Maha Rasas, Dhatus, (Metals) etc should be strictly followed and the procedures adopted must be specified in the report. Any metal or Rasa preparations should be subjected to animal toxicity for the export oriented products. Pharmacopeial guidelines should be followed for the formulations to be exported.
4. The proforma, utilized in the clinical trials of the formulations meant for exports should be provided along with the clinical reports copies of the Bio chemical investigations related to the patient population, included in the clinical study should also be enclosed.
5. The Pharmacy should considered the regulation under schedule 'J' of Drugs & Cosmetics Act 1940 while conducting the clinical trials for the products was submitting for licensing.
6. Classical Ayurvedic Concepts should be implemented in Clinical evaluations Preparation of Formulation & Standardization of products submitted for license.

7. Sources of Procurement of Crude Drugs / fresh plant material should be specified.
 8. Conspicuous display on the container of purely herbal and Ayurvedic Drug to be exported the words "Heavy Metals with in Permissible Limits" will be mandatory. Ayurvedic Drug Manufacturers who do not have in house laboratory facility shall get their drugs tested by any approved drug testing laboratory.
 9. Submission of the application for approval of the formulation will be summarily rejected, if any of the above guidelines from (I to VIII) suggested are not followed.
3. The Commissioner, Department of AYUSH, Hyderabad shall take necessary further action accordingly.

(BY ORDER AND IN THE NAME OF THE GOVERNOR OF ANDHRA PRADESH)

**P. CHANDRA SEKHAR,
EX-OFFICIO SECRETARY TO GOVT. (IN CHARGE)**

To
The Commissioner, Department of AYUSH, A.P. Hyderabad.
The Joint Secretary to GOI, Ministry of Health & Family Welfare,
Department of AYUSH, Red Cross Building-1,
Red Cross Road, New Delhi-1
Sf/Sc.

// FORWARDED BY ORDER //

SECTION OFFICER